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Ronald L Grudziecki
Burns Doane Swecker & Mathis
PO Box 1404
Alexandria, VA 22313-1404

EXAMINER

BAUM, STUART F

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 11/07/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,737

Applicant(s)

KAKIMOTO, TATSUO

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 4-6, 11 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-10, 12-22 and 24-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claim 1-27 are pending.
2. Applicant's election with traverse of Group I, claims 1-3, 7-10, 12-22 and 24-27, including SEQ ID NO:1 encoding SEQ ID NO:2, in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the instant application was filed under § 371, and Applicants believe that “unity of invention” exists in the instant case. Applicants’ rationale is that there is a greater sequence homology between two of their sequences than there is between their sequences and the art that was applied to break unity. In addition, Applicants assert that a “restriction between patentably distinct inventions is proper only where there is a serious burden of the Examiner to examine all the claims in a single application” (page 2 of the response). This is not found persuasive because Applicants are claiming a sequence with a homeodomain-like sequence, which is known in the art as evidenced by the Janssen et al paper. In regards to Applicants’ belief that there is not a serious burden on the Examiner to search all the claims; while the search of the prior art for one group may overlap with that of another, they are not co-extensive of each other and thus would be a burden on the office.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 4-6, 11, and 23 are withdrawn from consideration as being drawn to non-elected material.

Claims 1-3, 7-10, 12-22 and 24-27 are examined on the merits.

Specification

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01 (see for example, page 13, line 29).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-3, 7-10, 12-22, and 24-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation of “gene”. There is not a standard definition for this term, i.e., a gene can denote the coding region of an amino acid sequence or a gene can be defined as containing regulatory elements operably linked to the coding polynucleotide sequence encoding an amino acid sequence. If appropriate, the term “polynucleotide” can be used to denote nucleic acid molecules that encode a polypeptide. All subsequent recitations of “gene” are also rejected.

In claim 1, it is unclear if the gene or the amino acid sequence is involved in differentiation and has a homeodomain-like sequence. It is suggested that Applicant specifically specify what is being modified by “homeodomain-like” and “differentiation” using the phrase “wherein the (gene or amino acid sequence)” to replace the second “that”. It is suggested that

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Applicant also replace the first “that” with “wherein”. All subsequent recitations as discussed herein are also rejected.

In claim 1, the metes and bounds of “involved” cannot be determined since Applicant has not adequately defined this term. All subsequent recitations of “involved” are also rejected.

In claim 1, the metes and bounds of “homeodomain-like” cannot be determined since Applicant has not adequately defined this term. All subsequent recitations of “homeodomain-like” are also rejected.

In claim 7, it is unclear what conditions are required for the protein to “have(ing) an ability”. It is suggested that Applicant amend “having an ability to “wherein said protein induces..”. All subsequent recitations of “having an ability” are also rejected.

In claim 13, it is unclear what conditions are required for the protein to “has an ability”. It is suggested that Applicant amend “has an ability to “wherein said protein induces..”. All subsequent recitations of “has an ability” are also rejected.

In claim 16, the word “from” should be replaced with “in”.

In claim 16, the word “in” should be inserted after the first “or”.

In claim 16, the metes and bounds of “driving the expression of” cannot be determined since Applicant has not adequately defined this phrase. All subsequent recitations of “driving the expression of” are also rejected. Amending the claim to recite “transcribing”, instead of “driving the expression of” will obviate the rejection.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP

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§ 2172.01. The omitted steps are: wherein the expression of said gene induces differentiation in a plant or in a plant cell.

Claim 17 is indefinite in the recitation “inducing adventitious shoot formation from a plant cell”. It is physiologically impossible for a “plant cell” to form adventitious shoots.

Deleting “or a plant cell” will rectify the rejection.

In claim 17, the word “from” should be replaced with “in”.

In claim 17, the word “in” should be inserted after the first “or”.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: wherein the expression of said gene induces adventitious shoot formation in a plant.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: wherein the expression of said gene induces branching in a plant.

In claim 25, the word “from” should be replaced with “in”.

In claim 25, the word “in” should be inserted after the first “or”.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: wherein the expression of said gene induces differentiation in a plant or in a plant cell.

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Claim 26 is indefinite in the recitation “inducing adventitious shoot formation from a plant cell”. It is physiologically impossible for a “plant cell” to form adventitious shoots.

Deleting “or a plant cell” will rectify the rejection.

In claim 26, the word “from” should be replaced with “in”.

In claim 26, the word “in” should be inserted after the first “or”.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: wherein the expression of said gene induces adventitious shoot formation in a plant.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: wherein the expression of said gene induces branching in a plant.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 2-3, 18-22, and 25-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to a polynucleotide encoding a protein whose amino acid sequence is SEQ ID NO:2, including a vector and transformed host cell, plant, and plant cell and methods for inducing adventitious shoot formation and branching does not reasonably provide enablement for claims drawn to a method of inducing differentiation using

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the above nucleic acid sequence and to claims broadly drawn to a gene encoding a protein whose amino acid sequence has been modified by the addition or deletion of one or a plurality of amino acids and/or replacement with other amino acids in the amino acid sequence of SEQ ID NO:2, and methods of inducing differentiation, adventitious shoot formation and branching. Lastly, Applicant is not enabled for the claim drawn to a gene that hybridizes to a nucleic acid sequence of SEQ ID NO:1 or a portion thereof, under stringent conditions and that encode a protein that is involved in differentiation and has a homeodomain-like sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *In re Wands* factors (858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

Applicants isolated their invention from an activation tagging experiment using *Arabidopsis* in which transformed callus was screened for shoot growth when grown on non-shoot-inducing medium. The activated gene was plasmid rescued and used as a probe to screen a cDNA library constructed from calli exhibiting the activated-mutant phenotype. The cloned sequence was named Many Shoot (MSH) and is designated as SEQ ID NO:1 encoding SEQ ID

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NO:2 (page 14, line 17). Applicants over-expressed SEQ ID NO:1 in *Arabidopsis* and produced callus that regenerated adventitious shoots more rapidly than the control (page 16, lines 3-7) and a plant transformed with said sequence exhibited more branching than the control (page 16, lines 20-24).

It cannot be predicted by one of skill in the art that nucleic acids that have a modified sequence by the addition or deletion of one or a plurality of amino acids will encode a protein with the same activity as SEQ ID NO:2. Bowie et al (1990, Science 247:1306-10) teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of the protein to fold into unique three-dimensional structures that allows it to function and carry out the instructions of the genome. The cited reference also teaches that the prediction of protein structure from sequence data and, in turn, utilizing predicted structural determinations to ascertain functional aspects of the protein, is extremely complex (pg 1306, left column). Bowie et al teach that while it is known that many amino acid substitutions are possible in any given protein, the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three-dimensional structure/function relationship, and these regions can tolerate only conservative substitutions or none at all (pg 1306, right column). The sensitivity of proteins to alterations in even a single amino acid in a sequence is exemplified by McConnell et al (2001, Nature 411 (6838):709-713), who teach that the replacement of a glycine residue located within the START domain of either the PHABULOSA or PHAVOLUTA protein receptor with either an alanine or aspartic acid residue, alters the sterol/lipid binding domain. This change renders the protein constitutively active and

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therefore creates a dominant mutation which has a drastic alteration in phenotype compared to wild-type *Arabidopsis* plants.

The claims are broadly drawn to nucleic acid sequences that hybridize to SEQ ID NO:1 but Applicant has not provided guidance for selecting sequences that encode a protein whose function is the same as the encoded protein of SEQ ID NO:2. The state of the art teaches isolating DNA fragments using stringent hybridization conditions, does not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe. Fourgoux-Nicol et al (1999, Plant Molecular Biology 40 :857-872) teach the isolation of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65⁰C (page 859, left column, 2nd paragraph). Fourgoux-Nicol et al also teach that the probe and isolated DNA fragment exhibited a number of sequence differences comprising a 99bp insertion within the probe and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotide mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2). In the present example, the isolated fragment exhibits less than 50% sequence identity with the probe. In the present application, the selected sequences will encode proteins having modifications including additions, deletions, and substitutions of many amino acids when compared to a protein encoded by SEQ ID NO:1. Therefore, it is unpredictable as to whether any of the encoded proteins will induce adventitious shoot formation and branching when transformed into a plant. Absent any specific guidance as to criteria for selecting a DNA molecule encoding a protein having the

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desired function, one skilled in the art would not be able to use the claimed invention to generate plants with induced adventitious shoot formation and branching, without undue experimentation.

Applicant has not provided examples or guidance for selecting a sequence out of the multitude of sequences that are encompassed by Applicant's broad claim language, that gives the expected results when transformed into a plant. Transforming plants with heterologous genes that are involved in plant development produce unpredictable results. Kano-Murakami et al (1993, FEBS 334:365-368) teach introducing the *Oryza sativa* homeobox 1 (OSH1) gene into tobacco. OSH1 is a rice homologue of the *Knotted-1* homeobox gene from maize and would be encompassed by Applicant's broad claim language. Kano-Murakami et al teach transgenic tobacco plants comprising the OSH1 gene display a "range of phenotypes which include abnormalities in leaf and petal shape as well as stem height and number" (page 365, right column, 1st paragraph).

Applicant has broadly claimed a method for inducing differentiation. Differentiation encompasses all aspects of plant development including root growth, leaf development and flower development, just to name a few examples. Applicant's method only deals with adventitious shoot formation and branching, and has not been exemplified for any other aspect of plant development. The scope of Applicant's claims deals with adventitious shoot formation and branching, and therefore, method claims drawn to inducing differentiation are outside the scope of Applicant's enabled claims.

Therefore, given the breath of the claims; the lack of guidance and examples; the unpredictability; and the state of the art as discussed above, undue experimentation would be required by one skilled in the art to isolate a nucleic acid molecule encoding a protein exhibiting

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a modified sequence as compared to SEQ ID NO:2 and also possessing a homeodomain-like sequence, wherein transforming a plant with the nucleic acid molecule encoding said protein produces a plant having induced adventitious shoot formation and induced branching.

Written Description

7. Claims 2-3, 19-22, and 24-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a polynucleotide encoding a protein whose amino acid sequence has been modified by the addition or deletion of one or a plurality of amino acids and/or replacement with other amino acids in the amino acid sequence of SEQ ID NO:2, or to a gene that hybridizes to the nucleic acid molecule having the sequence as set forth in SEQ ID NO:1 or a portion thereof and that encodes a protein involved in differentiation and that has a homeodomain-like sequence. The specification only discloses the nucleic acid sequence of SEQ ID NO:1 encoding SEQ ID NO:2 and does not disclose any specific structural, physical and/or chemical properties for the modified claimed sequences. Applicant does not present a description of a homeodomain or a homeodomain-like sequence. While the claim recites functional language, the function cannot be ascertained because of the 112 second paragraph issues discussed above. It is unclear if all proteins exhibiting a homeodomain-like sequence will exhibit the recited function. Therefore, it does not appear that Applicant is in possession of the modified sequences or sequences that would hybridize to SEQ ID NO:1 under unspecified or

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under low stringency conditions. Therefore, one skilled in the art would not recognize from the disclosure that Applicant was in possession of the claimed invention. (see Written Description Requirement published in Federal Register/Vol.66, No. 4/ Friday, January 5, 2001/Notices; p. 1099-1111).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-3, and all subsequent dependent claims are directed to non-statutory subject matter. This rejection is made because the claims are drawn to “A gene” which does not indicate that the “hand of man” was involved in the invention. Amending the claim to recite “isolated” will obviate the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 2, 3, 20-22, 24, 25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Uberlacker et al (1994, Maize Genetics Cooperation Newsletter, No. 68, page 24).

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The claims are drawn to a gene encoding a protein whose amino acid sequence has been modified by the addition or deletion of one or a plurality of amino acids and/or replacement with other amino acids in the amino acid sequence of SEQ ID NO:2, the protein is involved in differentiation and has a homeodomain-like sequence. The claims are also drawn to a gene as specified above having the ability to induce branching, a vector comprising said gene, transformed host, transformed plant or plant cell and methods of inducing differentiation inducing branching in a plant. Applicants also claim a gene that hybridizes to a nucleic acid sequence of SEQ ID NO:1 or a portion thereof, under stringent conditions and that encode a protein that is involved in differentiation and has a homeodomain-like sequence.

Uberlacker et al teach a maize homeobox gene *Zmhox1b* that when transformed into tobacco produce developmental abnormalities including increased branching. Given that Uberlacker et al teach a homeobox gene, it would inherently comprise a homeodomain-like sequence and because it affects development, it is inherently involved in differentiation. The sequence of Uberlacker et al would be produced by modifying the DNA sequence so as to encode a protein comprising additions or deletions of one or a plurality of amino acids and/or replacements with amino acids in the sequence of SEQ ID NO:2. For purposes of molecular biology, the nucleic acid sequence would be in a vector and host cell and as such anticipate the claimed invention.

10. Claims 2, 3, 19, 21, 22, 24, 25, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Uberlacker et al (1996, *The Plant Cell* 8:349-362).

The claims are drawn to a gene encoding a protein whose amino acid sequence has been modified by the addition or deletion of one or a plurality of amino acids and/or replacement with other amino acids in the amino acid sequence of SEQ ID NO:2, the protein is involved in differentiation and has a homeodomain-like sequence. The claims are also drawn to a gene as specified above having the ability to induce adventitious shoots, a vector comprising said gene, transformed host, transformed plant or plant cell and methods of inducing differentiation inducing adventitious shoots in a plant. Applicants also claim a gene that hybridizes to a nucleic acid sequence of SEQ ID NO:1 or a portion thereof, under stringent conditions and that encode a protein that is involved in differentiation and has a homeodomain-like sequence.

Uberlacker et al teach maize homeobox genes *Zmhox1a* and *Zmhox1b* that when transformed into tobacco produce developmental abnormalities including adventitious shoots. Given that Uberlacker et al teach a homeobox gene, it would inherently comprise a homeodomain-like sequence and because it affects development, it is inherently involved in differentiation. The sequences of Uberlacker et al would be produced by modifying the DNA sequence so as to encode a protein comprising additions or deletions of one or a plurality of amino acids and/or replacements with amino acids in the sequence of SEQ ID NO:2. For purposes of molecular biology, the nucleic acid sequence would be in a vector and host cell and as such anticipate the claimed invention.

11. SEQ ID NO:1 encoding SEQ ID NO:2 is free of the prior art .

12. No claims are allowed

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the legal analyst, Sonya Williams, whose telephone number is (703) 305-2272.

Stuart Baum Ph.D.

November1, 2002


PHUONG T. BUI
PRIMARY EXAMINER
11/4/02